UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,216	01/20/2004	Stephen F. Kingsmore	36671-747.201	6434

80984 7590 11/06/2009

Inverness Medical Innovations / WSGR
Wilson Sonsini Goodrich & Rosati, P.C.
650 Page Mill Road
Palo Alto, CA 94304

EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
11/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,216	KINGSMORE ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-23 and 96-109* is/are pending in the application.

4a) Of the above claim(s) *5,6,9-18,20-23 and 96-108* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8,19 and 109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/7/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and remarks, filed 7/7/2009, are acknowledged. Claims 1 and 19 are amended. New claim 109 is added. Claims 1-6, 8-23, and 96-109 are pending. Claims 5-6, 9-18, 20-23, and 96-108 are withdrawn as being drawn to non-elected inventions. Claims 1-4, 8, 19, and 109 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 7/7/2009 has been considered. An initialed copy is enclosed.

Claim Rejections Withdrawn

The rejection of claims 1-4 and 19 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 12 of copending Application No. 11/690,767, is withdrawn in light of the abandonment of the copending application.

The rejection of claims 1-4, 8, and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of applicant's amendment thereto.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 8, 19, and newly submitted claim 109 are directed to an invention not patentably distinct from claims 1-5, 10, 15, 18, and 20-28 of commonly assigned application 11/543,312 and claims 1, 12, and 19 of commonly assigned application 11/770,608. The claims are not considered to be distinct for the reasons set forth below in the double patenting rejections.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned applications 11/543,312 and 11/770,608, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claims 1-4, 8, 19, and newly submitted claim 109 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 10, 15, 18, and 20-28 of copending Application No. 11/543,312 for the reasons set forth in the previous office action.

Applicant has not traversed this rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are drawn to methods of diagnosing severe sepsis in a human subject comprising determining the concentration of MPIF-1 (and TNF-R1) in a fluid test sample from a human subject and comparing the concentration of said analytes to a reference concentration so that the concentration of the analyte in the test sample is indicative of the presence of severe sepsis.

The claims of copending application 11/543,312 are drawn to methods of diagnosing severe sepsis by assaying CCL23 (which is an alternate name for MPIF-1) and sTNFR1a and diagnosing the presence of severe sepsis. The claims also include limitations where the sample is blood, serum, or plasma. This method would necessarily include a comparison to a reference concentration to determine whether the level was high enough to warrant the diagnosis. Applicant has added a limitation stating that an elevation of the analyte of about two-fold, relative to the reference concentration is indicative of the presence of severe sepsis. However, the fact that an elevation of two-fold (or four-fold) is indicative of severe sepsis does not add any method steps and is simply a fact that would be true whether it is recognized or not.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 8, 19, and newly submitted claim 109 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12, and 19 of copending Application No. 11/770,608 for the reasons set forth in the previous office action.

Applicant has not traversed this rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are drawn to methods of diagnosing severe sepsis in a human subject comprising determining the concentration of MPIF-1 (and TNF-R1) in a fluid test sample from a human subject and comparing the concentration of said analytes to a reference concentration so

that the concentration of the analyte in the test sample is indicative of the presence of severe sepsis.

The claims of copending application 11/770,608 are drawn to methods of diagnosing severe sepsis by assaying CCL23 (which is an alternate name for MPIF-1) and sTNFR1a and diagnosing the presence of severe sepsis. The claims also include limitations where the sample is blood, serum, or plasma. This method would necessarily include a comparison to a reference concentration to determine whether the level was high enough to warrant the diagnosis. Applicant has added a limitation stating that an elevation of the analyte of about two-fold, relative to the reference concentration is indicative of the presence of severe sepsis. However, the fact that an elevation of two-fold (or four-fold) is indicative of severe sepsis does not add any method steps and is simply a fact that would be true whether it is recognized or not.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Claim Rejections

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8, 19, and newly submitted claim 109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claims 1 and 19 to state that severe sepsis is indicated or diagnosed if the concentration of the analytes is elevated "about two fold" relative to the reference concentration. In claim 109, the concentration is elevated "about four fold" above the reference concentration. Applicant points to paragraphs 0011, 0012, 0145, and 0196 to provide support for these limitations. However, paragraphs 0011 and 0012 do not make any mention of

two fold elevations of any analyte. Paragraph 0145 states that possible markers for sepsis should show a two fold elevation and paragraph 0196 states that MPIF-1 shows a four fold elevation; however, neither of these paragraphs mention diagnosis of severe sepsis and paragraph 0196 states that some analytes were significantly lower in sepsis, which contradicts paragraph 0145. Therefore, the two fold and four fold limitations are new matter.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645